

CLAIMS

1. An analytical test device incorporating a dry porous
5 carrier to which a liquid sample suspected of containing
an analyte can be applied indirectly, the device also
incorporating a labelled specific binding reagent which
is freely mobile in the porous carrier when in the moist
state, and an unlabelled specific binding reagent which
10 is permanently immobilised in a detection zone on the
carrier material, the labelled and unlabelled specific
binding reagents being capable of participating in either
a sandwich reaction or a competition reaction in the
presence of the analyte, in which prior to the
15 application to the device of a liquid sample suspected of
containing the analyte, the labelled specific binding
reagent is retained in the dry state in a macroporous
body through which the applied liquid sample must pass en
route to the porous carrier material, the labelled
20 specific binding reagent being freely soluble or
dispersible in any liquid sample which enters the
macroporous body.

2. An analytical test device according to claim 1,
25 wherein the dry porous carrier material comprises a
chromatographic strip.

3. An analytical test device according to claim 1 or
claim 2, wherein the labelled specific binding reagent
30 comprises a specific binding reagent attached to a
particulate label.

4. An analytical test device according to claim 3,
wherein the particulate label is latex.

5. An analytical test device according to claim 4, wherein the latex comprises particles having a maximum dimension of not greater than about 0.5 micron.
- 5 6. An analytical test device according to claim 4 or claim 5, wherein the latex is coloured.
7. An analytical test device according to claim 4 or claim 5, wherein the latex is fluorescent.
- 10 8. An analytical test device according to any one of claims 1 to 7, wherein the macroporous body comprises plastics material.
- 15 9. An analytical test device according to any one of claims 1 to 8, wherein the macroporous body has an average pore size of not less than 10 microns.
- 20 10. An analytical test device according to any one of claims 3 to 9, wherein the macroporous body has a pore size not less than 10 times greater than the maximum particle size of the particulate label.
- 25 11. An analytical test device according to any one of the preceding claims, wherein the porous carrier material is nitrocellulose.
12. An analytical test device according to claim 11, wherein the nitrocellulose has a pore size of greater than about 1 micron.
- 30 13. An analytical test device according to any one of the preceding claims, wherein the macroporous body is in direct moisture-conductiv contact with the porous carrier material, and the detection zone in the porous carrier material is spaced away from the region of

contact of the porous carrier material with the macroporous body.

14. An analytical test device according to claim 13, wherein the quantity of liquid sample required to saturate the macroporous body is not less than the quantity of liquid sample capable of being absorbed by the mass of porous carrier material linking the macroporous body and the detection zone.

15. An analytical test device according to any one of the preceding claims, wherein the macroporous body and porous carrier are contained within a casing or housing constructed of moisture-impermeable material and having a sample entry port communicating with the macroporous body, the casing or housing also incorporating means to enable the detection zone to be observable from outside the casing or housing.

16. An analytical device according to any one of claims 1 to 14, wherein the porous carrier is linked via the macroporous body to a porous receiving member to which the liquid sample can be applied and from which the sample can permeate into the porous carrier.

17. An analytical device according to claim 16, wherein the porous carrier and the macroporous body are contained within a casing or housing constructed of moisture-impermeable material and the porous receiving member extends out of the casing or housing and can act as a means for permitting a liquid sample to enter the housing and reach the porous carrier, the casing or housing being provided with means which enable the detection zone of the porous carrier to be observable from outside the casing or housing so that the result of the assay can be observed.

18. An analytical device according to claim 17, wherein the casing or housing is provided with means which enable a further zone of the porous carrier to be observed from outside the housing and which further zone incorporates one or more control reagents which enable an indication to be given as to whether the assay procedure has been completed.

19. An analytical device according to either of claims 17 or 18, is provided with a removable cap or shroud which can protect the protruding porous receiving member during storage before use.

20. A pregnancy testing device comprising a hollow elongated casing containing a dry porous nitrocellulose carrier which communicates indirectly with the exterior of the casing via a bibulous urine receiving member which protrudes from the casing, the porous nitrocellulose carrier and the sample receiving member being linked via a macroporous body such that any sample reaching the porous carrier must first pass through the macroporous body, the sample receiving member and the macroporous body together acting as a reservoir from which urine is released into the porous carrier, the macroporous body containing a highly-specific anti-hCG antibody bearing a coloured direct label, the labelled antibody being freely mobile within the macroporous body and the porous carrier when in the moist state, and in a detection zone on the carrier spatially distant from the macroporous body a highly-specific unlabelled anti-hCG antibody which is permanently immobilised on the carrier material and is therefore not mobile in the moist state, the labelled and unlabelled antibodies having specificities for different hCG epitopes, the casing being constructed of opaque or translucent material incorporating at least one aperture through which the analytical result may be observed,

5911350 5911350

together with a removable and replaceable cover for the protruding bibulous urine receiving member.

21. A fertile period predetection device, as claimed in claim 21 except that the analyte is LH.

22. A device according to any one of the preceding claims, wherein the liquid sample is aqueous.

23. A macroporous body containing in the dry state a labelled specific binding reagent that is freely soluble or dispersible in an aqueous sample that may be applied to the macroporous body.

24. An analytical device incorporating a macroporous body according to claim 23, together with a test strip or the like into which liquid sample carrying dissolved or dispersed labelled specific binding reagent can flow from the macroporous body.

25. Use of a macroporous body according to claim 23 to facilitate the uptake of a labelled specific binding agent by a liquid sample before such a sample is analysed on a test strip or the like.

add
B2

30

35

add
C1
add H23
add C67